EXHIBIT B



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BY FEDERAL EXPRESS

Gejaa T. Gobena Civil Division Commercial Litigation Branch P.O. Box 261, Franklin Station Washington, DC. 20044 George B. Henderson, II Assistant U.S. Attorney John J. Moakley U.S. Courthouse 1 Courthouse Way, Suite 9200 Boston, MA 02110

Re: In re Pharmaceutical Industry Average Wholesale Price Litigation, MDL 1456

Dear Mr. Gobena and Mr. Henderson:

I write on behalf of the Track 1 Defendants in the above-referenced litigation ("Defendants") concerning current or former government employees, particularly of the Center for Medicare and Medicaid Services ("CMS"), who may testify at the upcoming November trial.

You will recall that Judge Saris asked the parties at the hearing on August 3 whether any current or former government employees would be called as witnesses at the trial in November, and if so, she noted that the parties should consider the implications of the so-called *Touhy* regulations. See 45 C.F.R. § 2 et. seq. These regulations set forth a procedure for notice of the intention to call a former government employee of an agency of the Department of Health and Human Services as a witness and for a response from the head of the relevant agency, in this instance the Administrator of CMS.

We have reviewed the regulations, however, and they are not applicable to this proceeding. The United States appears as a "consolidated plaintiff" on the docket, and it has moved to appear as an "interested party" in MDL No. 1456, a motion which was granted by the Court. Additionally, the United States has intervened in a matter, *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs.*, et al., which was recently transferred to MDL No. 1456 and is now pending before this Court. Accordingly, we do not believe the regulations are applicable. See id. at 2.1(d)(1).

The Defendants do intend to present one or more current or former employees of CMS as witnesses at trial. Even if the *Touhy* regulations were applicable here, which they are not, it is clear that any testimony from a current or former CMS employee would merit approval from the CMS Administrator. As you know, Judge Saris has expressed her desire to hear from such

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witnesses regarding the use of AWP as a basis for reimbursement of prescription drugs under Medicare Part B. Certainly, it would "promote the objectives of the Department," as provided in 45 C.F.R. § 2.3, to permit current or former employees of CMS to comply with the Court's request for testimony concerning these issues. The Defendants also believe that the testimony would be relevant to the development of a complete and accurate record on the issues presented for decision

If you would like to discuss the foregoing, we would be please to speak with you at your earliest convenience.

Very truly yours,

John T. Montgomery